The Environment Agency and Genetically Modified Organisms

R&D Project Record E2-040/PR

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Statement of Use
The aim of this project was to enhance the Environment Agency's understanding of the current and likely future direction of biotechnology developments, and to assess the implications they may have for the Agency's activities.

Key Words
Genetically modified organism; GMO; genetically modified micro-organism; biotechnology; environment; agriculture; herbicide tolerance; insect resistance; bioremediation; phytoremediation

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1   INTRODUCTION

1.1   Objectives of the Study

This report presents the findings of a research project undertaken on behalf of the Environment Agency into developments in genetically modified organisms:

The Environment Agency and Genetically Modified Organisms (R&D Project E2-040)

The overall objective of the project was to provide the Agency with sufficient knowledge and advice about GMOs to enable it to develop its view on their possible significance for Agency activities. Although not a 'front-line' regulator in the development, testing or marketing of GMOs, the Environment Agency nevertheless has an interest in the current and future direction of GMO developments because there are a number of areas in which such developments may impact upon issues in which it has a remit. These include waste regulation, integrated pollution control, diffuse pollution (particularly from agriculture), bioremediation of contaminated sites and biodiversity. These are set out in more detail in the Technical Report.

The aim of the project was to gather information on developments in order to enhance the Agency's understanding of the current and likely future direction of biotechnology developments, and to assess the implications these may have on the Agency's business. The intention is to inform the Agency's discussions with the principal regulators and those who develop and use GMOs, and enable the Agency to assess the contribution that such developments may have for sustainable development and the state of the environment. The research gathered available information, from an international perspective, on the nature of current GM activity. It covered techniques and products at various stages of development, from concepts at a fundamental research stage, through techniques in R&D or in pre-commercial evaluation, to products already approved for commercial use.

Genetic modification technology can give rise to novel products and applications, and there may also be implications from the production processes and procedures involved. Once approved for commercial use, experience abroad has shown that take-up can be rapid in certain economic sectors, and the implications for the environment could be positive, negative, neutral or unknown. Therefore, although the Environment Agency has no role in the direct regulation of genetic modification activities, it is nevertheless important that it keeps abreast of biotechnology developments and uses its advisory, regulatory and operational powers to ensure the environmentally sustainable application of the technology.

Scope of Project

Following discussions with the Agency's Project Board with responsibility for overseeing the project, it became apparent that there were three main areas of GMO applications which were likely to be of principal relevance for Agency functions. This was confirmed by our research.

The three areas are:

- agriculture, including horticulture, silviculture and animals;
- industrial processes and laboratory work using GMOs; and
- the use of GMOs for bioremediation.

1.2 Layout of the Technical Report

The Technical Report sets out the key findings of the research on current and future developments according to the three main areas - agriculture, industrial and laboratory processes, and bioremediation. Separate sections of the report deal with each of these three areas in turn, and each section gives an overview of the research findings in terms of the types of GMO products and technologies which are already commercialised, and those products or technologies which are currently being developed or are likely to be developed in the future. Where possible, an indication is given of the likely timescales to commercialisation, any barriers to commercialisation where these can be identified, and the likely take-up if the technology is commercialised. The report also describes the possible environmental consequences arising from the particular technology. Finally, an assessment is made of the implications for the Environment Agency of current and future developments.

The report also gives a large number of website addresses where further relevant information can be found, including:

- UK and international databases of GM products in trials or already on the market (see Annex A of Technical Report);
- the key organisations involved in the different areas of applications for GM products (see Annex A of Technical Report);
- sources of guidance and other reference material.

A number of ways are provided of accessing information in the document:

- hot links are provided to further information resources in the form of website addresses, typically where useful information is given on current approvals, or websites of key organisations involved in the development of GMOs;
- links through key words to parts of the text where further explanation or information can be found;
- links to a glossary and reference section.

2   APPROACH AND METHODOLOGY

The approach taken in this project was to draw together information available in an international arena, on products and techniques in development or already commercialised. The research covered:

- concepts at a fundamental research stage;
- techniques subject to R&D prior to commercial development;
- products/techniques subject to evaluation and testing (including field trials) before being brought to market; and
- products/techniques already approved in some countries.

The research was based on published sources, primarily via Internet websites but also from scientific and technical journals. Interviews were also carried out with individuals within key organisations. The information obtained was then reviewed to identify those GM technologies of principal relevance to the Agency, on the basis of its functions and duties and also on the likely timescales and extent to which the applications may be brought forward for commercialisation in the UK, and on their relevance and likely take-up in the UK.

2.1   Internet Research

The research revealed that there is a very large amount of information publicly available on GMO products and technologies. Internet websites which carry information include the following:

- company websites, generally giving information on products and product types, and commercial and research interests;
- academic and other research institution websites, giving information on research programmes and lines of individual research;
- regulatory databases of product approvals (for trials and marketing) in the UK and beyond;
- news services reporting developments, usually on individual products or regulatory processes;
- a wide variety of websites of organisations and individuals, including non-governmental organisations and single-interest or pressure groups, mainly giving opinion and comment but also providing fora of links to other websites.

Any relevant and useful websites are referenced within the text of the Technical Report, and a list of websites of the key players is given in Annex A. The web addresses are current at the time of writing (June 2001) but it should be noted that these might change over time.

2.2   Journal Searches

For the journal search, the project initially compiled an extensive list of journals which could carry relevant information on developments in GMO technologies and products.

These included business or trade journals, environmental publications and scientific journals. However, it quickly became apparent that this would produce a vast number of references and

a potentially unmanageable amount of wide-ranging information. It was decided to restrict the search to those journals specifically covering genetic modification technologies and products and associated commercial or research developments. Searching wider than this tended to produce information which was either too focused (for the purposes of this project) on the detailed science of particular research lines, too focused on regulatory mechanisms and regimes, or too subjective or qualitative to be helpful. The specific journals which were used were:

- Nature;
- Nature Biotechnology;
- Genetic Engineering News; and
- New Scientist.

2.3   Face-to-Face, Telephone and Email Interviews

Over a period of two months, 58 interviews were held with key organisations and individuals. These covered the main companies involved in development of GMO products, the key research institutions and the main UK regulators (DEFRA [1]   and HSE). Most of the interviews (32) were by telephone, but some (20) were done by email and some (6) face-to-face. Two thirds of the interviews were with organisations and individuals in the UK and one third overseas (mainly other European countries, US, Canada, South America, Asia, Australia and New Zealand). Only 9 of the contacts were unable to offer any substantive information.

2.4   Workshop for Environment Agency Staff

A workshop was held for Agency staff on 27 November 2001, to present the interim findings of the research and to provide an opportunity to discuss the possible implications for the Agency. Several individuals from external organisations were also invited to participate in the workshop, either to present information on developments in their particular field, or simply to provide an external perspective and contribute information where relevant. The workshop provided a useful forum for checking that the technologies of principal interest were covered in sufficient detail, and also for confirming with participants where the main implications for Agency functions are likely to be.

The overheads which were presented at the workshop are reproduced for information in Annex A of this Project Record.

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(1) At the time the interviews took place, interviews were held separately with the Department of Environment Transport and the Regions (DETR) and the Ministry of Agriculture Fisheries and Food (MAFF)

3   AGRICULTURE

3.1   Summary of Developments and Timescales

The following table summarises the main areas of development with respect to GMOs in agriculture, and gives estimated timescales for their commercialisation.

Table 3.1   GM Applications to Agriculture: Summary of Applications and Timescales to Commercialisation

Product	Stage of Development	Approximate timescale to market globally	Approximate timescale to market in UK
Crops			
Herbicide tolerance	Commercialised	On market	< 5
Fungal resistance	Research	5	5-10
Viral resistance	Commercialised	On market	5-10
Insect resistance in crop	Commercialised	On market	10 +
Insect control with predators	Research	?	?
Insect control with viruses	Research	?	?
Nematode resistance	Research	5 - 10	?
Quality traits	Various stages	Some on market, various	1-5
Controlled fertility	Commercialised	On market	Ready for market in UK if moratorium lifted
Stress tolerance	Research	10 +	10 +
Gene-switching	Research	5 - 10	5 - 10
Smart plants	Research	10 +	10 +
Plants as feedstocks	Research	?	?
Pharmaceuticals in plants	Research	5	?
Trees			
Modified lignin	Research	1-5 years	10+ years, but subject to change in certification criteria, otherwise unlikely to be commercialised in UK
Increased growth rates	Research	5-10 years	As above for modified lignin
Herbicide tolerance	Research	1-5 years	As above for modified lignin
Insect resistance	Research	1-5 years	As above for modified lignin
Improved timber quality	Research	10+ years	
Animals			
Farm animals for food	Research	?	?
Fish for food	Commercialised	On market	?
Farm animals for pharmaceutical production	Research	0-2	1-5
Farm animals for organ transplants	Research	?	?

3.2   Issues of Relevance to the Environment Agency

Our research suggests that a number of environmental benefits are possible from the use of biotechnology, but there is as yet very little hard data to confirm or discount these, especially

data with relevance to the UK. At the same time, the potential environmental risks are considerable, and similarly little data on these are available. The Agency needs to be aware of the many areas of uncertainty, whether taking a view on the technology as a whole or on particular applications. The main environmental risks and benefits are summarised in Table 3.7 below. Those of particular relevance are highlighted in bold text.

We suggest that the following areas of biotechnology development should be closely monitored by the Agency, in liaison with or through the existing competent authorities and advisory committees.

3.2.1 Herbicide Tolerance

Herbicide tolerance is a priority for a number of reasons. The technology is already commercialised in several countries, and is ready for commercialisation in the UK if the voluntary moratorium ends; it is a trait put into a least three crops of UK relevance (oilseed rape, beet and fodder maize) and although these crops between them do not account for a large percentage of UK crops, there is no guarantee that it will not be put into wheat which would then account for a significant percentage of the UK cropping area; it could see rapid uptake by farmers; the broad spectrum herbicides involved have implications for aquatic environments; there could be benefits in terms of replacement of more toxic or mobile chemicals.

However, as outlined above, there is still considerable uncertainty over timescales for commercialisation, rate of uptake, and the 'real life' scenarios for chemical change. This provides an opportunity for preparatory action in advance of future developments, for example identifying areas likely to be most sensitive to contamination with broad spectrum herbicides and offering guidance to farmers and growers. Existing guidance, for example the SCIMAC guidelines, might provide an appropriate vehicle for provision of such advice.

The issue of obviating currently-used agro-chemicals also needs consideration. Scenarios for chemical replacement have been presented by those developing the technology and others such as research institutions.

Such information deserves further examination, as does data from overseas on chemical replacement (bearing in mind that the agronomic conditions are not always comparable).

There may be merit in developing more detailed scenarios, or in conducting other research for example into the likely responses of farmers. It should be noted that these kinds of impacts should come under the remit of the Advisory Committee on Releases to the Environment (ACRE) and the Advisory Committee on Pesticides (ACP) and therefore close links with both Committees would be beneficial.

Going further, it is possible to envisage that in future, developments in GM technologies could be driven in part by environmental considerations. For example, it would be possible to identify currently used agro-chemicals which cause environmental problems, and encourage alternative strategies which might be achievable through GM techniques. However, there would need to be careful evaluation of risks and benefits before such an approach was taken, and even so there may still be public opposition to GM technology as a process (as distinct

from the products arising from that process). The ACRE sub-group on good practice might be an appropriate forum to approach to take this idea forward. Another possibility might be the more proactive provision of advice to the Advisory Committee on Pesticides, in terms of suggesting which pesticides should be targets for replacement and/or phase-out, and where GM strategies might have environmental benefits over the currently used chemical strategies.

On the biodiversity implications of GMHT crops, much weight is being put on the results of the Government's Farm Scale Evaluations. The Agency might consider how far it wants to have an involvement in the consideration of biodiversity impacts and future decision-making, particularly for aquatic biodiversity given the Agency's duty in this area. If there is strong interest, it might be appropriate to seek greater involvement in the scientific process for the Farm Scale Evaluations. It should be noted that impacts on biodiversity will not be unique to GMHT crops, but at the same time, the results of the FSEs will not necessarily be transferable to other types of crops and traits.

Although gene flow is also an issue for GMHT crops (although not unique to GMHT), it is outside the scope of the Agency's conservation duties.

3.2.2   Insect, Fungal and Viral Resistances

In common with herbicide tolerance, the main issue here for the Agency is replacement of currently-used pesticides. A number of positions on the issue could be considered: one of simply noting and welcoming reductions in use of particular chemicals; engaging in more formal and detailed 'risk/benefit' analyses as part of a regulatory or pre-regulatory discussion; or proactively encouraging the replacement of particular chemicals. As with herbicide tolerance, issues regarding the direct ecological effects of these crops (e.g. effects on pest species, recombination of viruses) and gene flow are somewhat outside the Agency's current remit.

3.2.3 Gene Switching

This technology seems to be further away than the two categories above, but a consideration may be the environmental impacts of the chemicals used to activate or de-activate genes. If the technology tends towards a particular chemical and the crop varieties are taken up widely, there is a possibility of increased or novel uses of particular chemicals.

This is an area where pro-active involvement with the scientific and regulatory debates is strongly recommended, to guide the use of appropriate chemicals from the beginning. There should not be a repeat of the antibiotic resistance scenarios, where the impact of the widespread use of these markers was not fully considered by regulatory committees until they were present in a wide range of products coming forward for commercial approval.

3.2.3 Smart Plants

Smart plants can indicate to the grower their need for inputs, for instance fertilisers or water. This is some years away in commercial terms, but could be an opportunity for the Agency to put its concerns on the research agenda, for instance needs for chemical cleanup and solutions to eutrophication.

3.2.5 Fish

All the indications at present are that transgenic fish would not get commercial approval in the UK . However, because of the implications for aquatic environments of escape of transgenic fish, wherever they are produced, and given the Agency's fisheries and aquatic biodiversity duties, it is strongly recommended that Agency should keep this situation under continual review, and maintain liaison with ACRE to monitor developments closely.

3.2.6 Animals

There is a small (in scale) amount of work producing pharmaceutical products from animals, but we could not find any evidence of work on transgenic animals for food production of short-term relevance to the UK. There appear to be no novel waste implications to the first category, but the second should be kept under review.

3.2.7 Monitoring

The Agency should be considering, with the competent authorities, what role it might have in the on-going monitoring of the impacts of GM releases, which will be a legal requirement under the new Deliberate Release Directive 2001/18/EC should commercialisation proceed in the UK. This applies to all GM releases and therefore all the applications listed below, but is particularly relevant for GMHT crops given the possible multiple effects.

Table 3.2   Summary of Main Potential Environmental Risks and Benefits from Use of GMOs in Agriculture

Product	Main potential environmental risks	Main potential environmental benefits
Crops		
Herbicide tolerance	**Contamination of surface waters with herbicide run-off;** greater control of weeds leading to less food for farmland wildlife; spread of introduced genes to wild species	**Reduction or obviation of herbicides with greater environment impact;** later control of weeds giving potentially improved biodiversity; reduced tillage giving potentially greater biodiversity and lower energy use
Fungal resistance	**Non-target effects, including decreased ability of soil micro-flora to degrade plant material;** spread of introduced genes to wild species.	**Reduction or obviation of fungicides with negative environmental impacts**
Viral resistance	Creation of new viruses; spread of introduced genes to wild species	**Obviation of pesticides used to control virus vectors, e.g. aphicides**
Insect resistance in crop	Non-target effects, particularly multi-trophic effects; build-up of insect resistance; spread of introduced genes to wild species	**Obviation of insecticides;** reduced effect on non-target species; **elimination of spray-drift;** reduced energy use
Insect control with GM viruses and GM insects	Viruses affecting species outside target host-range; unknown impacts on ecosystems	**Obviation of insecticides;** reduced effect on non-target species
Nematode resistance	Effects on soil micro-flora; spread of introduced genes to wild species	**Reduction or obviation of nematicides**
Quality traits	Possible changes in palatability to pests, which could lead to greater pest outbreaks; **possible land use impacts; possibility of changes to starches in potatoes making them more frost-tolerant and therefore more weedy.**	None foreseen
Controlled fertility	None foreseen	None foreseen
Stress tolerance	Spread of genes to wild relatives; encroachment of crops in wild habitats; **changed distribution of crops**	**If drought tolerance, less use of water**
Gene-switching	**Environmental implications of chemicals used to trigger traits;** spread of genes to wild relatives	**Obviation of particular treatments e.g. anti-sprouting treatments;** containment of transgenes
Smart plants	Spread of genes to wild relatives	Lower inputs of water, fertiliser
Plants as feedstocks	**Changes in land use;** spread of genes to wild relatives; unknown effects on food chains	**Replacement of polluting industrial processes; lower contribution to global warming**
Pharmaceuticals in plants	**Changes in land use;** spread of genes to wild relatives (if uncontained); unknown effects on food chains	**Replacement of polluting industrial processes**
Trees		
Modified lignin	Spread of genes to wild relatives	**Obviation of chemicals used for de-lignification**
Increased growth rates	Spread of genes to wild relatives	None foreseen
Herbicide tolerance	**Same as for crops, above**	**Same as for crops, above**
Insect resistance	Same as for crops, above	**Same as for crops, above**
Improved timber quality	None foreseen	None foreseen
Animals		
Farm animals for food	None foreseen, unless knock-on effects on waste streams	None foreseen, unless knock-on effects on waste streams
Fish for food	**Escape and interbreeding with wild relatives; out-competing wild relatives**	**If disease resistant, obviation of chemical treatments**
Farm animals for pharmaceutical production	None foreseen, unless knock-on effects on waste streams	None foreseen, unless knock-on effects on waste streams
Farm animals for organ transplants	None foreseen, unless knock-on effects on waste streams	None foreseen, unless knock-on effects on waste streams

3.2.8 Research Needs

There are still uncertainties in many areas relating to the likely impacts of the introduction of GM technologies into UK agriculture. The following highlights some of the more significant areas where further research is needed to fill the gaps. The Agency may or may not be the appropriate body to undertake such research. Current contacts and liaison with existing competent authorities and advisory committees may be the most effective route to some of this information and therefore these should be maintained.

- *Specific environmental impacts.* There are a number of areas where questions are still unanswered about the actual environmental impacts of the technologies. These include the risk of gene flow to other species, the impacts on insect populations including non-target organisms, the possible build-up of tolerance to insecticides, the impact of specific and broad spectrum fungal resistance and nematode resistance on the decay of crop residues, and others.

- *Impacts relative to other technologies.* The environmental impacts also need to be considered in the context of current technologies or alternative technologies, and the relative significance evaluated. For example, is introduction of GM worse than the effects of introduction of alien species? Are GM technologies a more effective way to reduce agrochemical use than organic practices? Would the impact of GMHT crops on herbicide use be any different from conventionally-bred HT crops? This is especially important in considering arguments about the possible GM contribution to more 'sustainable' agriculture - there is no widely accepted definition of what 'sustainable' agriculture is, or how relatively 'sustainable' the range of current farming practices are.

- *Large-scale impacts.* It is still unclear what will be the larger scale impacts from the introduction of GM technologies in agriculture, for example the likely density of coverage of GM crops in a given area or the size of any shifts in agrochemical use. These are dependent on a number of unknown factors, including: the speed and level of take-up of GM crops among farmers (which will be influenced at least in part by public attitudes and the existence of sufficient markets for GM foods); the actual changes in spraying regimes in practice. The use of models could be a helpful tool for predicting the impacts of different scenarios, for example the Agency has developed a model for predicting pesticide pollution of the aquatic environment ('POPPIE').

There are also uncertainties regarding impacts on cropping patterns, for example changes in rotations which may be permitted by new tolerances to disease, or environmental tolerances which allow crops to be grown on land previously not viable for those crops.

There is thus a need for a framework to judge the impacts and overall sustainability of GM technologies in agriculture. While ACRE advises on the release of GMOs into the environment, it only judges the risks. However, it is not evident that a risk/benefit analysis of GM crops is possible yet. Given the gaps in information which have been identified above, it is clear that there are still a number of key areas where there are no scientific certainties about the individual environmental impacts, let alone the wider issues of management practices and other variables.

There is also a need to view GM products in a wider UK and EU agricultural context. The strongest influence on the UK agricultural sector is the Common Agricultural Policy, and this is likely to continue to be the main driver of environmental impacts of agriculture in future.

4   INDUSTRIAL AND LABORATORY PROCESSES

4.1   Summary of Developments and Timescales

The following table summarises the main areas of development with respect to GMOs in industrial and laboratory processes, and gives estimated timescales for their commercialisation.

Table 4.1   GM Applications to Industrial and Laboratory Processes: Summary of Applications and Timescales to Commercialisation

Product	Stage of Development	Approximate timescale to market globally	Approximate timescale to market in UK
Industrial Processes			
Bacteria	Commercialised and in use in UK production	On market	On market
Fungi	Commercialised, but not common in UK production	On market	On market
Yeasts	Commercialised, but not common in UK production	On market	On market
Mammalian cells	Commercialised, but not common in UK production	On market	On market
Animals for pharmaceutical production	In development, some drugs in clinical trials	?	?
Plants for pharmaceutical production	Research	5	?
Laboratory Uses			
Bacteria	Widespread use	On market	On market
Viruses	Widespread use	On market	On market

4.2   Issues of Relevance to the Environment Agency

4.2.1 The Main Environmental Issues

As many of the activities undertaken in industrial and laboratory processes using GMOs do not need to be notified to the competent authorities, then a full assessment of the environmental implications is not possible, beyond the statutory risk assessment. Furthermore, the potential environmental impacts of such novel organisms are not well understood, particularly indirect and longer term impacts. However, it should be noted that there is not yet any recorded incidence of environmental damage from the accidental release of 'contained use' GMOs.

The main environmental issues include:

- what the environmental risks are from laboratory and industrial processes, including what GMOs are used and possibility of survival in the environment;
- how the environmental risks have been assessed, including how the potential for environmental harm has been assessed;
- what containment measures are generally employed and their effectiveness;
- what the waste streams are, both nature and scale; and
- what environmental consequences are possible from the waste streams, including deactivated waste streams.

Biotechnology, including genetic modification, also offers the potential for improvements to industrial processes, which could lead to reduced consumption of energy and other resources and less hazardous waste generation. There is also the potential for the development of new waste treatment technologies, leading to improved discharges to the environment.

4.2.2 Implications for Agency Roles and Functions

It is important that the current dialogue with the competent authority is maintained. Improved coordination and agreement between organisations will enable the Agency to be more aware of the range and scale of current processes and the types of organisms typically used. It will also allow the Agency to contribute to discussions and consultation on regulatory and policy issues on areas where there is environmental significance, such as risk assessments, containment and waste management. In addition, any opportunities between the two organisations to share the complementary skills areas of GMMs and environmental protection are likely to bring benefits to both organisations. It is recommended that the Agency also keeps abreast and informed of the work of ACRE, particularly in respect of risk assessment issues and any implications for waste management.

Because of the large number of premises involved (particularly in laboratory work), the range of organisms and modifications, and the uniqueness of the risks for each process and application, many of the processes inevitably have to be self-monitoring. There may nevertheless be opportunities for the Agency to make an input to the work of the competent authority, in order to work towards minimising the environmental risks. For example, the Agency might become involved at the stage of process development and initiation, to work with companies to develop good practice [1] . It may be pragmatic for the Agency to promote the increased adoption of environmental management systems by industries and laboratories. This would bring benefits in terms of minimising impacts and better management of risks. In addition, increased take-up of the European Eco-Management and Audit Scheme (EMAS) or a shift from ISO 14001 to EMAS would also bring benefits through the requirement for public reporting of environmental information.

4.2.3 Research Needs

There is a lack of available information on the processes which exist at both laboratory and industrial scale, because of the lack of a regulatory requirement for notification of most processes involving GMOs. There are also uncertainties regarding the environmental significance involved in issues such as risk assessment, containment and waste management (including the likelihood of post-release survival and the environmental implications of this) and how these are dealt with by those responsible for evaluating that significance and taking decisions on it.

In combination, these two areas of uncertainty mean that it is not possible to be certain of the nature and scale of any environmental impacts arising from the industrial and laboratory use

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[1] A starting point for such work would be *the ACGM Compendium of Guidance: Guidance from the Health and Safety Commission's Advisory Committee on Genetic Modification*. This is available at http://www.hse.gov.uk/hthdir/noframes/acgmcomp/acgmcomp.htm.

of GMOs. There is a need for better awareness and understanding in both of these areas to enable the Agency to be clearer about the environmental significance of these activities, whether there is a need to take a more proactive role and where any efforts might be most effectively directed. For example, the following studies would produce useful information for the Agency:

- a SWOT analysis of the industry;
- a review of available information on behaviour of GMMs in the environment;
- a review, jointly with the competent authority, of environmental best practice, current standard practice and options for containment and waste management;
- a review, in conjunction with the competent authority, of how the Agency can add value to work on dealing with environmental uncertainties, risks and impacts.

5   BIOREMEDIATION AND PHYTOREMEDIATION

5.1   Summary of Developments and Timescales

The following table summarises the main areas of development with respect to GMOs in bioremediation and phytoremediation, and gives estimated timescales for their commercialisation.

Table 5.1   GM Applications to Industrial and Laboratory Processes: Summary of Applications and Timescales to Commercialisation

Product	Stage of Development	Approximate timescale to market globally	Approximate timescale to market in UK
Biosensors			
GM lux biosensors (biosensors with luminescence)	Commercialised and in use by bioremediation companies	On market	Already being used by bioremediation companies within the UK within their "package" of bioremediation services. Not available for purchase off-the-shelf: approximate timescale 5-10 years.
Biosensors using body movement as a sensor of toxicity	Research	10-15 years	10-15 years
Ammonia-specific biosensor	Research	5-10 years	5-10 years
Biosensors to detect illicit drugs	Research	5-10 years	5-10 years
In vitro technology	Research	10+ years	10+ years
Bioremediants			
PCB degrading super-bacteria	Research	5-10 years	5-10 years
Phytoremediants			
Heavy metal accumulators and transporters (e.g. in US, absorption of cadmium by Arabidopsis)	Research	1-5 years	5-10 years
Heavy metal rejectors	Research	5-10 years	5-10 years
Plants as bioremediators of toxins in soils	Research	On market	On market

5.2   Issues of Relevance to the Environment Agency

Although a relatively niche concern compared with GM developments in the agricultural and horticultural sectors and although not a priority part of ACRE's work programme, the implications which genetic modification could have for the bioremediation and phytoremediation sectors will be of interest to the Environment Agency. This is because the Agency has an important regulatory role regarding contaminated land including the provision of information and advice on good practice to local authorities. The Agency's policy is to promote remediation of contaminated land and encourage the use of effective remedial

technologies, including bioremediation where relevant. It will also facilitate the remediation of contamination at orphan Special Sites. The Agency provides guidance on land contamination to other organisations such as DEFRA, English Nature, English Heritage and the equivalent Welsh bodies. Thus in carrying out these duties, the Agency has a clear interest in keeping abreast of any developments using GMOs which could enhance the techniques and tools available for the remediation of contamination.

The most interesting use of genetic modification is likely to be within the biosensor sector where the lux biosensor, for example, could provide major breakthroughs in detecting environmental toxins, particularly in the context of stricter regulation and tighter environmental controls which can limit the effectiveness of current toxicity tests. The general consensus is that this biosensor will be ready for market in 1-5 years, however the political climate and public opinion will determine whether this timescale is extended.

There are cases where only GM bioremediants will be able to clean-up long-lived chlorinated compounds, for example on military or industrial sites, and therefore this is one area which the Environment Agency should be particularly aware of.

From our research the main findings and conclusions to be drawn are:

- GM technologies are likely to provide the major path forward for biosensors; in terms of bioremediants, they will provide one tool in a toolbox;

- the first EPA approval to release recombinant strains of bioremediant microorganisms in the US has already been given;

- political and public opinion are likely to be the main determinant of the timescale to market for most GM bioremediation products in the UK;

- their intended mode of use (i.e. field release versus use in a contained laboratory) is likely be a material factor in the timescales to approval for commercial use. Most interviewees seemed confident that the soil (or other contaminated substrate) will be brought to the microbe, rather than the other way around;

- there appears to be little independent research and assessment done on the environmental implications of these genetically modified products, particularly for soil ecology.

5.2.1   Research Needs

There appears to be a certain lack of consensus around certain aspects of bioremediation and phytoremediation, and also some areas where information is scant. The following areas could usefully be examined in more depth in order to clarify areas of uncertainty regarding the environmental risks and benefits:

- the risk assessments which have been carried out, and how the risk has been assessed;
- the available evidence on the environmental impacts, their significance and any consequences;

- how bioremediants and phytoremediants are regulated (contained use or deliberate release), how this is implemented and whether this is effective in dealing with the environmental impacts;
- related to the previous issue, clarification of the interface between regulation of GMOs and the legislative framework for contaminated land and its remediation.

6   CONCLUSIONS AND RECOMMENDATIONS

6.1   The Main Findings

The main developments in each of the three main areas are set out below, and the issues of most relevance to the Agency are identified. As well as the specific issues in each of the three areas, there is a general consideration, which applies to all issues of relevance to the Agency, and that is the need for further research on the following:

- specific environmental impacts, where there are still considerable uncertainties around the consequences of gene flow, effects on non-target species and effects on soils;
- relative environmental impacts, e.g. the effects of GM-based agriculture relative to those of conventional or organic agriculture;
- large scale, cumulative impacts, where the scale of uptake results in a certain threshold being reached (for example the cumulative impact of widespread use of a single herbicide, resulting in diffuse pollution levels exceeding environmental quality standards).

There is also a need for a framework within which to judge the impacts and overall sustainability of GM technologies.

6.1.1 Agriculture

Agriculture is the area of greatest significance for the Environment Agency, in terms of the likely scale of the impacts if the use of GMOs is permitted. Herbicide tolerance is the trait closest to commercialisation in the UK, and is likely to remain a central part of biotechnology company strategies for some years to come. It presents a range of environmental issues including changes to patterns of chemical use; resulting possible effects on chemical concentrations in surface and ground water; flow of genes to wild relatives; and indirect effects on biological diversity.

Next in line for commercial application are fungal and viral disease resistances, and insect resistances, although the latter is of less relevance to the UK than some other countries thanks to the (presently) cool climate. Alongside possible environmental consequences such as gene flow and effects on non-target species, these developments may facilitate reductions in currently used chemicals.

Another major category of traits is for product quality changes such as oil or starch characteristics. These transformations raise fewer obvious environmental issues, but they need to be explored case-by-case.

Developments such as stress tolerances, gene-switching to turn traits on and off, smart plants that indicate their own need for inputs, and plants producing pharmaceuticals and chemical feedstocks are further off. Some may present important environmental benefits in terms of reduction in use of resources such as chemicals and energy; some present issues of changes to land use on a large scale.

GM trees and grasses are the subject of extensive research outside the UK, but their relevance and acceptability in the UK is in doubt. In terms of animals, research on fish is the furthest advanced, but again acceptability in the UK is doubtful. There are still considerable uncertainties over the environmental impacts, and also of the likely significance of these at the larger scale.

It must be noted that the potential environmental impacts depend on how the technology is applied in any given agricultural system and situation, rather than the technology per se.

The key developments and timescales to commercialisation are summarised in Table 3.1.

Issues of Relevance to the Agency

The main considerations for the Agency are as follows:

1. The possibility of large-scale changes to agro-chemical application regimes, particularly those resulting from the introduction of herbicide tolerant crops, and the consequent implications for surface and groundwater quality. There are two main functional challenges for the Agency:

   - ensuring that the potential impacts of these changes are taken into account in the approvals process, given the uncertainties surrounding timescales to commercialisation, likely uptake of the technology if it is commercialised, and how growers might manage the crops in practice;

   - ensuring that the Agency has all the right institutional links to ensure that its views on such impacts are taken into account in decisions. This means continued membership of the Advisory Committee on Pesticides (ACP), developing the present links with the Advisory Committee on Releases to the Environment (ACRE) and establishing a relationship with the Agriculture and Environment Biotechnology Committee (AEBC).

2. Given the Agency's general conservation duties, the extent to which it should be involved in the biodiversity implications of genetic technology, particularly implications for aquatic biodiversity. These include indirect impacts from changes to chemical regimes and more direct impacts such as gene flow, for example from genetically modified fish. The Agency should consider how far it should comment on the conduct of, and the results of, the Farm Scale Evaluations.

3. Ensure a watching brief on the possible UK application of genetic modification in fish, trees and forage and leisure grasses, since all of these could have large-scale impacts on water quality and water use. This means continuing to monitor developments outside the UK (chiefly in the US) and maintaining close links with the appropriate advisory and regulatory bodies (chiefly ACRE).

4. The general issue of principle for the Agency as to whether, if GM technologies appear to offer real environmental benefits in terms of reduction of chemical, water and energy inputs, the Agency should promote these, and whether, looking further into the future, it

should actually encourage particular applications of genetic technology in agriculture. In reaching such decisions, the Agency would need to weigh such benefits against risks and uncertainties, and take into account levels of public acceptance of the technology.

6.1.2 Industrial and Laboratory Processes

The most common industrial processes using GMOs in the UK concentrate on GM bacteria and this is expected to continue, although the use of GM mammalian cell cultures is expected to increase in the future. Scales of production vary from hundreds of litres to tens of thousands of litres, and it is possible in the near future that some processes will be over 1 million litres. In laboratory processes, GM applications involve the use of mainly bacteria and viruses, but with a wide variety of transformations being used for a wide range of applications, often as a tool in other research. It is expected that the use of GM viruses will increase. The environmental implications of the use of GMOs in industrial and laboratory processes are not well understood, and there are significant gaps in information and understanding.

The key developments and timescales to commercialisation are summarised in Table 4.1.

Issues of Relevance to the Agency

1. How environmental risks and the potential for environmental harm are assessed, including in some cases a general lack of information on which environmental risks can be assessed.

2. The effectiveness of containment measures, given that the definition of containment has been widened under the revised regulations.

3. The nature and scale of GM waste streams (including deactivated waste streams) and their environmental consequences.

4. Uncertainties about the possibilities and risks of accidents.

5. Agency relationships with the key regulators and advisory committees.

6.1.3 Bioremediation and Phytoremediation

The main areas of development are in biosensors, remediation using GM micro-organisms and remediation using plants and trees. GM biosensors are in use currently in the UK, and are likely to be of most interest to the Environment Agency. The use of GMOs in bioremediation and phytoremediation could provide new tools for dealing with currently intractable contamination, however commercialisation in the UK is at least 5 years away.
Although the environmental benefits from such applications of GMO technologies are clear, there appears to have been little research done on the environmental risks, particularly on soil ecology.

The key developments and timescales to commercialisation are summarised in Table 5.1.

Issues of Relevance to the Agency

1. The scope for development of biosensors and bioremediants to deal with wastes and contaminants of particular interest to the Agency, and how far to promote these if there are still issues relating to public acceptance of the technology.

2. The risks and merits of field releases of GMOs for bioremediation, compared with keeping contaminated soils in containment for their treatment.

4. The long term and cumulative implications for soil ecology, including the difficulty of modelling effects on soils.